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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,556	02/01/2000	Eric H. Kuhrts		5012

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/06/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/495,556

Applicant(s)

KUHRTS, ERIC H.

Examiner

Liliana Di Nola-Baron

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1615

DETAILED ACTION

Receipt of Applicant's amendment, filed on February 21, 2003, is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 51-93, 99-101 and 106 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Regarding claims 51-93 and 106, the amendment to the claims adding the limitation "without added water" represents a departure from the specification and the claims as originally filed and Applicant has not pointed out where the support comes from. In page 12 of the specification, last paragraph, Applicant teaches that buffering agents can be added to the composition and process of the invention as additives. Buffering agents contain water, therefore the limitation "without added water" in the claims represents a departure from the specification and claims as originally filed.

4. Regarding claims 58-60, 73-75, 87-89 and 99-101, the phrase "of about" represents a departure from the specification and the claims as originally filed and Applicant has not pointed out where the support comes from. Original claims 11-13 provide support for an amount of sugar from 1-30% by weight and original claims 19-21 provide support for an amount of oil from 3 to

Art Unit: 1615

30%, however, the expression "of about" reads on values such as 2.98 or 2.99, for which there is no support. It is suggested to amend the claims to read on the phrase "from" instead of "of about".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 51-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steber et al. (U.S. Patent 4,837,381).

The claimed invention is directed to microencapsulation processes comprising adding a core material and an oil into a mixer, mixing them until microencapsulated particles are formed and discharging the particles, and pharmaceutical compositions comprising microencapsulated core material. The dependent claims are directed to the processes or compositions of generic claims, further comprising a sugar or a mineral.

Steber et al. provides compositions comprising a fat or a wax having melting points higher than 40°C (104 Deg. F.) or mixtures thereof and a biologically active protein, peptide or polypeptide, including growth hormone and growth factors, and slow release compositions comprising said compositions (See col. 2, lines 15-59). Steber et al. includes vegetable waxes, and specifically

Art Unit: 1615

sugar cane (which contains 15-20% of sucrose), and mineral waxes among the waxes used in the invention (See col. 2, lines 60-68). Thus, the compositions disclosed by Steber et al. comprise a core material mixed with an oil and further comprising a sugar and/or a mineral. Steber et al. teaches that the microspheres of the invention are dispersed in animal or vegetable oil and metal compounds may be added to the compositions (See col. 3, lines 28-54 and col. 4, lines 28-46). Specifically, Steber et al. includes soybean oil among the vegetable oils used in the invention (See col. 5, lines 21-31). Steber et al. provides a process for preparing the microspheres of the invention, said process comprising mixing the active ingredient with the fat, wax or mixtures thereof, forming microspheres and cooling (See col. 5, lines 32-50). The preparation of injectable microspheres in Example 1, #2, is performed by mixing the active ingredient with the fat, wax or mixtures thereof, spraying the mixture through a spray nozzle equipped with a heated jacket and cooling the formed microspheres. Thus, the process disclosed by Steber et al. comprises adding a core material and an oil into a mixer, mixing them until microencapsulated particles are formed and discharging the particles, as claimed in claims 51-57, 61, 63, 65-72, 76, 78, 94-98, 102, 104 and 106 of the instant application. Regarding claims 80-93, the patent is deficient in the fact, that it does not specifically disclose the speed used in the mixer, however, one of ordinary skill in the art would have determined the optimal speed by routine experimentation. With respect to Applicant proviso that no classification step is performed during the microencapsulation process, Example 1, #2 in Steber et al. teaches that collection of the microspheres on a series of sieves is done only after the microencapsulation process is completed, thus no classification step is performed during the microencapsulation process. With respect to the amount of oil claimed in the instant application (claims 58-60, 73-75, 87-89 and 99-101), Steber et al. teaches that the

Art Unit: 1615

microspheres contain the active agent in 40-95% of oil and claim 17 in the patent discloses a composition obtained by heating 1-30% of growth hormone and 5-60% of fat or wax or mixtures thereof, dispersing said mixture in oil and cooling the composition. With respect to the amounts of sugar and mineral in the composition and process claimed in the instant application (claims 62, 64, 77, 79, 91, 93, 103 and 105), the patent is silent regarding the amounts of sugar cane and mineral wax used in the invention, however, one of ordinary skill in the art would have been able to determine the optimal concentration range by routine experimentation. With respect to the iodine value claimed in claim 107, the patent is silent about the iodine value of the oils used in the invention, however, it contemplates using soy oil (See for example Table VIII), and one of ordinary skill in the art would have been able to determine the optimal iodine value by routine experimentation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Steber et al. to device processes for the encapsulation of biological material and compositions comprising the microencapsulated material. The expected result would have been a successful process and successful compositions. Because of the teachings of Steber et al., that the process of the invention is successful in forming compositions for the controlled release of drugs, one of ordinary skill in the art would have a reasonable expectation that the processes and compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments, filed on February 21, 2003, with respect to the rejection of claims 51-64 under 35 U.S.C. 112, first paragraph, have been fully considered and are persuasive, since the specification does not disclose any classification step. Therefore, the rejection has been withdrawn.

8. With respect to the rejection of claims 58-60, 73-75, 87-89 and 99-101, original claims 11-13 provide support for an amount of sugar from 1-30% by weight and original claims 19-21 provide support for an amount of oil from 3 to 30%, however, the expression "of about" reads on values such as 2.98 or 2.99, for which there is no support. It is suggested to amend the claims to read on the phrase "from" instead of "of about".

9. The support in the specification added by Applicant's amendment filed on February 21, 2003 and based on original claims 1-29, and the amendment to claims 57, 70, 72, 84, 86, 94, 96 and 98 have overcome the 35 U.S.C. 112, first paragraph rejection of claims 62, 64, 77, 79, 91, 93, 94, 103 and 105, and second paragraph rejections of claims 57, 70, 72, 84, 86, 96 and 98 of the previous Office action. Accordingly, said rejections are withdrawn.

10. Applicant's arguments with respect to the 35 U.S.C. 112, first paragraph rejection of claims 80-93 and second paragraph rejection of claims 51 and 68 have been fully considered and found persuasive, since Applicant has pointed out the support in the specification for the work input claimed in claims 80-93, and clarification for the classification step recited in claim 51 and the mixer work input recited in claim 68. Accordingly, said rejections are withdrawn.

11. Applicant's argument with respect to the 35 U.S.C. 103(a) rejection of claims 51-106 of the previous Office action have been fully considered and found persuasive, since the prior art

Art Unit: 1615

teaches a process wherein the material is encapsulated in a polymer, rather than in oil, as claimed in the instant application. Accordingly, said rejection is withdrawn. However, upon further consideration, a new grounds of rejection is made in view of Applicant's amendment adding the limitation "without added water".

Conclusion

12. Claims 51-107 are rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.



April 29, 2003

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600